

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

IN RE:)	
)	
KAREN E. HART, R.PH.)	
License No. 2000156876)	Complaint No. 2018-000033
P.O. Box 104)	
Cleveland, MO 64734)	

SETTLEMENT AGREEMENT

Come now Karen E. Hart, R.Ph. ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that she understands the various rights and privileges afforded her by law, including the right to a hearing of the charges against her; the right to appear and be represented by counsel; the right to have all charges against her proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against her; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against her and, subsequently, the right to a disciplinary hearing before the Board at which time she may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against her license. Being aware of these rights provided her by operation of law, Respondent knowingly

and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to her.

Respondent acknowledges that she has received a copy of the draft Complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 2000156876, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent Karen E. Hart is licensed by the Board as a pharmacist, License No. 2000156876. Respondent's license is, and was at all times relevant herein, current and active.

3. At all times relevant hereto, Respondent was employed as a float pharmacist based out of Wal-Mart Pharmacy 10-0096 in Harrisonville, MO ("Wal-Mart 10-0096").

4. She administered vaccinations at Wal-Mart Pharmacy 10-2955, 1701 West 133rd Street, Kansas City, MO 64145 ("Wal-Mart 10-2955" or the "Pharmacy") in October, 2017.

5. On or about January 4, 2018, Board Inspector Elaina Wolzak conducted a routine inspection of the Pharmacy.

¹ All statutory references are to the Revised Statutes of Missouri 2016 unless otherwise indicated.

6. During her inspection she reviewed the Pharmacy's vaccination records.
7. The Pharmacy's Standing Order protocol for 2017-2018 was signed by the protocol physician on August 14, 2017 and had an effective date of August 17, 2017.
8. The Standing Order stated it expired on August 24, 2018.
9. Respondent signed the Standing Order protocol at Wal-Mart 10-0096 on October 26, 2017.
10. Respondent signed the Standing Order protocol at Wal-Mart 10-2955 on December 7, 2017.
11. Respondent administered eight vaccinations between October 9, 2017 and October 19, 2017 at the Pharmacy without having signed the Standing Order protocol at the Pharmacy.
12. The eight vaccinations Respondent administered at the Pharmacy were five Influenza Virus vaccines, two Prevnar 13 vaccines, and one Zostavax vaccine.
13. Respondent indicated that she was unaware that the protocols had to be signed every year.
14. Missouri law gives a licensed pharmacist the authority to give immunizations, to wit:

1. The "practice of pharmacy" means . . . the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by a physician for a specific patient as authorized by rule; . . . § 338.010.1, RSMo.

15. However, Missouri law imposes the following requirements in order for pharmacists to be authorized to give immunizations as set forth in 20 CSR § 2220-6.050, which provides in relevant parts:

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.

* * *

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures . . .
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;

4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

16. Respondent violated § 338.010.1, RSMo, 20 CSR § 2220-6.050(1), (4)(F)-(G) and (5)(A)-(B) by administering eight vaccinations without a signed immunization protocol.

JOINT CONCLUSIONS OF LAW

17. Respondent's conduct is cause for disciplinary action against her license to practice pharmacy under §338.055.2(5), (6), (13) and (15), RSMo:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any

holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

* * *

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

A. Respondent's license, License No. 2000156876, is hereby **PUBLICLY CENSURED.**

B. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except

by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

C. Respondent, together with her heirs and assigns, and her attorneys, does hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

<u> </u>	REQUESTS
<u> </u>	DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO PRACTICE PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that

the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

RESPONDENT

KAREN E. HART

Karen E. Hart, PharmD
Karen E. Hart

Date:

11/14/18

PETITIONER

MISSOURI BOARD OF
PHARMACY

By:

[Signature]
Kimberly Grinston
Executive Director

Date:

12.10.18

NEWMAN, COMLEY & RUTH P.C.

By:

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